

Testimony Submitted by

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On behalf of the
American College of Obstetricians and Gynecologists

Submitted to the
House Energy and Commerce Health Subcommittee

For the Hearing Entitled
**Use of Imaging Services: Providing Appropriate Care for
Medicare Beneficiaries**

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Statement of Douglas W. Laube, MD, MEd
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On behalf of the American College of Obstetricians and Gynecologists (ACOG) and our 49,000 physicians and partners in women's health, I would like to thank Chairman Deal and members of the Energy and Commerce Health Subcommittee for the opportunity to discuss the use of ultrasound in our specialty and the importance of this technology to the women we serve. I am the Chair of the Department of Obstetrics and Gynecology at the University of Wisconsin and the current President of the American College of Obstetricians and Gynecologists.

I would like to focus on the imaging most used in my specialty – ultrasound. We believe the safety and longstanding integration of ultrasound in medical offices sets it apart from other forms of imaging and warrants special consideration in this debate.

Medicare patients make up only 13% of the average ob-gyn practice. This small but significant percentage includes both older women and women with disabilities of all ages. While today's hearing is focused on imaging in Medicare, the decisions about Medicare policy this Committee may make will be adopted widely by private payers, Medicaid and TRICARE, the health care system for 9 million military families. Clearly, women of all ages throughout the country stand to be affected by these decisions.

Medical imaging is a complex subject. Discussions of growth and safety of imaging must clearly distinguish between different types of imaging. Setting it apart from other imaging, ob-gyn ultrasound has an unquestioned record of safety, is fully integrated in day-to-day patient care, and is a critical part of medical resident education. A distinction between ultrasound and the rest of the imaging field, including CT, MRI, and PET, is warranted. **We urge the Congress, in any legislation, to recognize the safety, quality and appropriateness of**

ultrasound studies and to exempt ultrasound from any new restrictions on imaging use, federal quality standards, or additional administrative burdens.

Unique Characteristics of Ultrasound

Ultrasound uses low intensity sound waves to generate images. Most people are familiar with obstetric ultrasound as a way to evaluate the health of a fetus in utero. But ultrasound has broader application and value in obstetrics and gynecology and across several medical specialties. In obstetrics, ultrasound is useful in accurately dating a pregnancy, estimating the amount of amniotic fluid and detecting birth defects. Ultrasound may be necessary if there is a complication during labor or to identify an ectopic pregnancy, a life-threatening condition. In gynecology, ultrasound is used to identify the cause of unexplained pain or bleeding, to visualize a mass felt during a manual exam and in the assessment of infertile patients.

Ultrasound has been established as an accurate imaging modality for many conditions. Other specialties use sonography to identify cysts or tumors in the breast, look for causes of abdominal pain, investigate causes of joint pain, or identify an enlarged prostate. In some conditions requiring a biopsy, ultrasound can be used to guide needle placement and eliminate the need for surgery. Ultrasound is also used to guide the needle placement during amniocentesis to reduce the risk of maternal or fetal injury.

Ultrasound has many advantages over other types of imaging. Since it does not use ionizing radiation or contrast media, to which some patients are allergic, it is extremely safe. Ultrasound does not require sedation and is performed non-invasively, eliminating risk of infection and other potential adverse events. Portable or hand-carried equipment allows scans to be performed in an ob-gyn's exam room to capture real-time images, including fetal

movement and umbilical blood flow. Critical clinical data are immediately available to the physician making patient care decisions. Its non-invasiveness, convenience for physicians and patients, and real-time precision have made ultrasonography an essential tool for early diagnosis of disease and quality health care.

Ultrasound is an essential part of ob-gyns' clinical care. With several decades of clinical use, ultrasound is fully integrated into patient care. Removing this tool from the exam room or creating burdensome new requirements for physicians who use it will only bring harm to patients who want and need timely diagnosis and accurate information. Congress should reject proposals to restrict the use of this tool.

Ultrasound is different from other imaging services for several reasons:

- Ultrasound is safe;
- Training is incorporated into residency and board exams for many physician specialties and all ob-gyns;
- Use of ultrasound saves money and improves quality; and
- Growth of ultrasound is appropriate and is no faster than growth in other Medicare Part B services.

These many important differences lead us to the conclusion that proposals in the imaging debate are unnecessary for ultrasound.

Ultrasound is Safe

The first consideration in the use of any technology should be its safety. Diagnostic ultrasound uses low intensity sound waves to generate images, unlike x-ray, CT and nuclear medicine, which require ionizing radiation, a potential carcinogen. Additionally, ultrasound

does not require the use of contrast media, which are required for angiography and some CT studies, and cause adverse events in a significant number of patients.

After many years of widespread clinical use, the FDA (among others) has found no known harmful effects associated with the medical use of ultrasound¹. Studies in humans have revealed no direct link between the use of diagnostic ultrasound and any adverse outcome. It is the general consensus that the clinical benefits of ultrasound far outweigh any potential risk.

In particular, ACOG has carefully investigated the safety of scanning during pregnancy. In this regard, we concur with the FDA statement that "ultrasonic fetal scanning is generally considered safe and is properly used when medical information on a pregnancy is needed. But ultrasound energy delivered to the fetus cannot be regarded as completely innocuous. Laboratory studies have shown that diagnostic levels of ultrasound can produce physical effects in tissue, such as mechanical vibrations and rise in temperature. Although there is no evidence that these physical effects can harm the fetus, public health experts, clinicians, and industry agree that casual exposure to ultrasound, especially during pregnancy, should be avoided. Viewed in this light, exposing the fetus to ultrasound with no anticipation of medical benefit is not justified."²

ACOG has taken a firm position against the non-medical use of ultrasound and is alarmed by the emergence of imaging centers whose sole use of ultrasound is for entertainment, or 'keepsake' ultrasound, a practice that ACOG does not endorse.³ ACOG has advised several

1 U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration: An Overview of Ultrasound: Theory, Measurement, Medical Applications, and Biological Effects. Publication # FDA 82-8190

2 U.S. Food and Drug Administration, Center for Devices and Radiological Health, Diagnostic Devices Branch. Fetal Keepsake Videos. Available at: <http://www.fda.gov/cdrh/consumer/fetalvideos.html>.

3 ACOG Practice Bulletin No. 58, Ultrasound in Pregnancy; ACOG Committee Opinion No. 299, Guidelines for Diagnostic Imaging During Pregnancy; ACOG Committee Opinion No. 297, Nonmedical Use of Obstetric Ultrasound; American Institute of Ultrasound in Medicine. 1999. Prudent Use; American Medical Association, H480-955: "Keepsake" Fetal Ultrasonography.

imaging centers of our position and at ACOG's urging some imaging manufacturers have adopted similar positions.

Ob-Gyns are Well-Trained and Well-Qualified to Perform Ultrasound Exams

Taking ultrasound out of the ob-gyn office is akin to taking away the stethoscope, it is so integrated with the care ob-gyns provide, particularly in the treatment of pregnant women. Procedures performed by ob-gyns include sonography to assist in the diagnosis of certain pregnancy complications, diagnosis and management of certain gynecological cancers, sources of pelvic pain or postmenopausal bleeding. Maternal-fetal medicine specialists, who work with high-risk pregnant women, are trained in the use of fetal echocardiography to investigate fetal heart problems. Patients requiring advanced imaging procedures--such as MRI, CT and PET--are generally referred to a radiologist.

Residency Education

Since 1982, ultrasound has been recognized as an essential element of ob-gyn training. Training in ultrasound begins early in residency and continues throughout. The manual for the American Residency Coordinator in Obstetrics and Gynecology (ARCOG) specifies that by the end of the first year of training, ob-gyn residents must learn ultrasound physics and be able to perform time scanning and interpretation under supervision. By the end of the second year, ob-gyn residents observe and perform advanced ultrasound procedures under supervision and can interpret sonograms. In the third year, residents are expected to be able to identify normal anatomy on transvaginal ultrasound, as well.

In addition, the American College of Graduate Medical Education ob-gyn residency requirements explicitly state that educational curriculum must include obstetric and gynecologic ultrasonography and other imaging techniques. Under guidelines from the

Council on Resident Education in Obstetrics and Gynecology (CREOG), graduating ob-gyn residents must be able to understand and independently perform diagnostic ultrasonography. The American Board of Obstetrics and Gynecology tests extensively on this subject in certification and recertification exams.

Obstetric ultrasound has been in ob-gyn offices for so long that radiology residents see very little of it in their training. One study found that radiology residency programs provided fewer than 4 weeks per year of obstetric sonography and that radiology residency and fellowship lecture topics were similarly deficient. The authors concluded that for radiology residents “current levels of experience in obstetric sonography may not be providing sufficient experience to allow residents to appropriately manage call cases or for practicing radiologists to provide such services after their training is completed.”⁴

The Role of Specialty Societies in Ensuring Quality

ACOG, and other specialty societies, offer many opportunities for postgraduate medical education in ultrasound through seminars and meetings. In addition, several specialties have developed appropriateness criteria or other guiding principles in the use of imaging technology. ACOG has several publications to educate Fellows on appropriate usage of this technology. Practice Bulletins offer guidance on choosing a transducer; differentiation between standard, limited and specialized examinations; the indications and parameters for first, second and third trimester ultrasound; and proper documentation of the scan. These criteria were published in the journal *Obstetrics and Gynecology* and are widely available to our members. In addition, ACOG has worked with the American Institute of Ultrasound in Medicine (AIUM)

4 CJ Kasales et al. Training in Obstetric Sonography for Radiology Residents and Fellows in the United States. *American Journal of Roentgenology*. 2001; 177: 763-767.

and with the American College of Radiology (ACR) to develop clinical practice guidelines for antepartum obstetrical, female pelvic and saline infusion sonohysterography.

When specialty societies see the need for further education, training can be developed to fill the gap. To facilitate the incorporation of ultrasound into surgical practice, the American College of Surgeons developed an ultrasound education program consisting of didactic and hands-on learning.⁵ It consists of a basic, core module that covers ultrasound physics, instrumentation and scanning technique, and clinical applications. The basic core module is a prerequisite for education in the advanced training modules. There are advanced training modules in acute or trauma, vascular, abdominal, anorectal, head and neck, and breast ultrasound. Questions are included on the American Board of Surgery qualifying and in-service examinations that require the interpretation of ultrasound images.

Use of Ultrasound Saves Money and Enhances the Quality and Safety of Care

Use of ultrasound in clinical care speeds decision-making and enables greater reliance on minimally invasive, less costly, procedures. Many exams need to be performed urgently, such as when a woman experiences unexplained bleeding, pelvic pain or discovery of a mass. Ectopic pregnancies or complications during active labor can be life threatening and require immediate ultrasonography so the patient can be cared for quickly. Ob-gyns are the most appropriate physicians to provide these services. Radiologists often are not on call throughout the night and on weekends when many emergencies occur. It is critical that women have access to diagnosis and treatment when they need it.

⁵ ED Staren, MM Knudson, GS Rozycki, JK Harness, DC Wherry, SR Shackford. An evaluation of the American College of Surgeons' ultrasound education program. American Journal of Surgery. 2006. 191(4):489-96.

In ob-gyn, as in many other specialties, ultrasound has eliminated the need for “exploratory” surgery or invasive diagnostics to make the same determination. In many cases, integration of ultrasound can have considerable cost savings, in addition to quality of care and patient benefits.

- Continuous ultrasound guidance improves the safety of third trimester amniocentesis and reduces costly complications. In one study, ultrasound guidance helped achieve a 99% success rate, considerably higher than the 87% success of the procedure in previous studies without using ultrasound guidance.⁶ Prior to ultrasound guidance, complications were common and often serious, including premature rupture of membranes, infection, maternal hemorrhage, fetal or placental hemorrhage, fetal distress and fetal injuries.
- Ultrasound imaging in clinical practice enables a breast surgeon to perform a minimally invasive breast biopsy and determine whether the lump is cancerous in a matter of days. Previously a surgeon had to do an open biopsy and the patient waited as long as 10 days to learn the result. The Medicare program is estimated to have saved as much as \$88 million because of the use of image-guided breast biopsies instead of open biopsies between 2001 and 2003.⁷
- Use of transvaginal ultrasound as the initial diagnostic test to evaluate peri- and post-menopausal women with abnormal vaginal bleeding has been found to yield substantial cost-savings over biopsy-based treatments. Endometrial biopsy is a relatively inexpensive test for identifying endometrial cancer but is a poor test for diagnosing benign endometrial abnormalities. Transvaginal ultrasound is more sensitive to these

⁶ MC Gordon, K Narula, R O'Shaughnessy, W Barth. Complications of Third-Trimester Amniocentesis Using Continuous Ultrasound Guidance. *Obstetrics and Gynecology*. 1999. 99 (2). 255-259.

⁷ An Analysis of the Use of Ultrasound Imaging Services in the Medicare Program, The Lewin Group, May 27, 2005

benign conditions, proving itself to be a cost-saving, minimally-invasive alternative to biopsy.⁸

In other examples:

- Ultrasound guidance of central venous catheterization (CVC) placement reduces the risk of devastating complications by 75%.
- Point of care evaluation of torso trauma resulted in decreased mortality and reduced inpatient length of stay. A conservative estimate of the resulting savings is \$569 million per 100,000 patients.⁹
- A study examining endoscopic ultrasound with fine needle aspiration for preoperative staging of esophageal cancer resulted in potential cost reductions of \$12,340 per patient by reducing the total number of thoracotomies performed.¹⁰
- Point of care, limited ultrasound during evaluation of patients for cardiac conditions revealed sufficient information for clinical decision making in 80% of cases. The remaining 20% received a detailed cardiac ultrasound. Using this staged approach, total costs were reduced by 33% and time to diagnosis was reduced from four days to instantaneous.¹¹
- Thyroid nodules are a common occurrence. The usual approach to diagnosing these nodules is fine needle aspiration biopsy. When ultrasound guidance is used for these biopsies, the success rate of the procedure jumps from 75% to 94% avoiding a costly

8 Medverd JR, Dubinsky TJ. Cost analysis model: US versus endometrial biopsy in evaluation of peri- and postmenopausal abnormal vaginal bleeding. *Radiology* 2002;222(3):619-27.

9 Effect of Early Ultrasound on Outcomes of Trauma Patients, *Acad Emerg Med* 2000, 7:501

10 Impact of endoscopic ultrasound combined with fine-needle aspiration biopsy in the management of esophageal cancer, *Endoscopy*. 2003 Nov;35(11):962-6.

11 Clinical utility and cost effectiveness of a personal ultrasound imager for cardiac evaluation during consultation rounds in patients with suspected cardiac disease, *Heart*. 2003 Jul;89(7):727-30.

hospital-based open biopsy.¹² The cost of using ultrasound each time – roughly \$150 – compared with the cost of an open biopsy – approximately \$2900 – shows that using ultrasound routinely in these cases could save \$40,000 per 100 patients.

- A 2003 study by the UK's National Institute for Clinical Excellence and published in *The British Medical Journal* found that patients experience fewer complications when providers use ultrasound imaging to guide insertion of the catheters. Economic modeling showed that using ultrasound to place central venous catheters would save £2000 for every 1,000 procedures. This included the costs of purchasing ultrasound machines and training medical staff.¹³

Growth in Ultrasound Utilization

In its March 2005 Report to Congress, MedPAC estimated overall imaging growth to be at a rate of 10.1%, compared to a 5.2% overall growth rate in Medicare physician services between 1999 and 2002. This analysis fails to differentiate between the growth rate of ultrasound versus the growth rate of advanced imaging and does not adequately reflect savings from in-office ultrasound. Further analysis of the data show that MedPAC also may have understated overall growth in Medicare services, making imaging growth seem larger by comparison.

Ultrasound imaging in the physician office grew slower than imaging services in general (8.9% versus 10.8%). Ultrasound imaging services also grew slower than all Medicare Part B services (7.2% versus 7.8%) when looking across physician and outpatient settings. For some

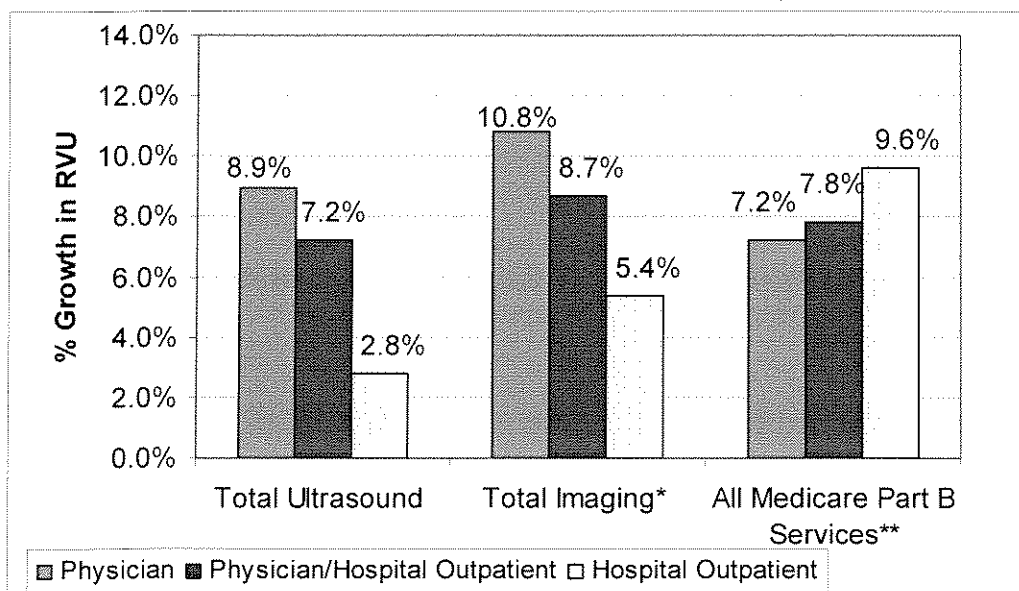
12 Efficacy of Ultrasound-Guided Fine-Needle Aspiration Biopsy in the Diagnosis of Complex Thyroid Nodules, *The Journal of Clinical Endocrinology & Metabolism*, Vol 86, No. 9 4089-4091.

13 The Effectiveness and Cost-Effectiveness of Ultrasound Locating Devices for Central Venous Access: A Systematic Review and Economic Evaluation, Calvert N, Hind D, McWilliams RG, Thomas SM, Bererley C, Davidson A; *Health Technology Assessment* 2003; 7 (12), National Institute for Clinical Excellence, March 2003

categories of ultrasound services, such as the ultrasound codes billed by ob-gyns for diagnosis of gynecologic conditions, the growth in this three-year period has been less than 4% a year.

The overall Part B growth rates used in the analysis by the Lewin Group differ significantly from those reported by MedPAC in its March 2005 report to Congress (which cited a 4.3% average annual growth rate from 2001 to 2002). This difference is primarily explained by our inclusion of all Medicare services, where MedPAC compared imaging growth to only selected types of physician services. In particular, MedPAC did not include durable medical equipment, or the “Other” category in its analysis. (The “Other” category consists primarily of high-growth chemotherapeutic drugs for cancers, other drugs and biologicals covered under Medicare Part B, and ambulance services.) Additionally, our analysis is based on all Medicare

Table 1
Average Annual Growth in Volume of Medicare Part B Services across Providers
from 1999-2003 (Based on 2005 RVUs)



Source: The Lewin Group's analysis of the Medicare Physician/Supplier Master Summary File.

* Total Ultrasound includes BETOS categories I3A-I3F

**Total Imaging includes BETOS categories I1A-I4B

*** All Medicare Part B Services includes all BETOS categories, including drugs, durable medical equipment, and ambulance services. Growth in Hospital Outpatient Services spending is estimated by using growth in allowed charges deflated by the hospital market basket. This is then weight averaged with the growth in physician services, using total allowed charges for the weights, to estimate growth in All Medical Services for Physician/Hospital Outpatient

Part B claims, while MedPAC used physician claims from a 5-percent random sample of Medicare beneficiaries.

Explaining Growth: Shift in Site of Service

Lewin found that the application of ultrasound by different specialties is appropriate to their patient populations, as well as a shift in ultrasound services from the hospital into the physician's office, which benefits patients in terms of convenience and accelerates diagnosis and treatment.

Table 1 reflects the average annual growth in physician- and hospital-billed services for the period from 1999 to 2003. The differences between the growth rate in physician-billed services and the combination of physician- and hospital-billed services indicates, in part, a shift in site of service. For ultrasound in particular, the numbers suggest services were shifting out of hospital outpatient departments towards physicians' offices. The same trend, and potential shift in site of service, is not evident in all Medicare services. Significant growth continued in all sites of service over the 1999 to 2003 time period.

As much as 19-21% of the growth in the technical component of ultrasound imaging is attributable to the shift in site of service, contributing significantly to the appearance of growth in these services. But a significant share of the perceived growth may not be growth at all, but a simple one-for-one substitution of scans that were previously performed in the hospital outpatient department and are now performed in the physician's office.

Understanding Utilization: Incidence of Diseases

The increase in the incidence rate (per 1,000 population) of the diseases for which ultrasound imaging is useful has increased in recent years. Some of these increases have been quite substantial, such as a cumulative increase of more than 20% in the incidence of

gallbladder, pancreatic, and liver disease over a four-year period. These diseases may be diagnosed using ultrasound on the abdomen or pelvis region.

Some of this increase may also be an increase in the rate of detection. Medicare began covering annual prostate exams and prostate-specific antigen (PSA) tests in 2000, which is in the period of our data, and per-population use of prostate ultrasound increased 5% between 1999-2001 and not at all from 2001-2003. It is reasonable to believe that the new coverage resulted in an increase to a higher level of utilization of follow-ups to PSA tests, including prostate ultrasound and ultrasonic guidance of prostate biopsy (as discussed below), but that once that adoption had happened, further increases above the current level may not result.

Outside of Medicare, pregnancy rates are soaring in women older than age 35, and these women are more likely to have pregnancy complications, including hypertension and diabetes. Babies born to older mothers are more likely to be born preterm or with a low birthweight. The risk of miscarriage doubles and the older a woman gets, the greater her risk of carrying a child with chromosomal abnormalities. Ultrasound would be indicated for any one of these factors, and many older mothers should expect several ultrasounds and possibly ultrasound-guided tests such as amniocentesis or chorionic villus sampling (CVS).

Appropriateness

In looking at most utilization data, the question remains: how do you distinguish appropriate utilization from inappropriate utilization? What part of growth is better access to screening or more people living longer with chronic disease, and what part is a redundant use of health care resources? Public and private payers struggle with these questions. But until we better know how to answer these questions, Congress, CMS and MedPAC should recognize that it is premature to label all growth as bad growth.

For instance, ultrasound-guided needle biopsy allows a physician to diagnose breast cancer without an open incision. The patient is spared time in the operating room, increased risk of infection, days off work and scarring. But on the Part B side of the ledger, two additional ultrasounds are scored—one for diagnosis and one to guide the needle. Marrying the hospital outpatient fee schedule and the physician fee schedule costs shows that needle-guided breast biopsy saves Medicare millions of dollars, but looking at the physician fee schedule alone shows only the cost of two additional ultrasounds.

In a study assessing appropriateness, conducted for Highmark Blue Cross Blue Shield, ob-gyns ranked highest among physician specialties in appropriateness, followed closely by urology, another specialty that has integrated the use of ultrasound in their practice.¹⁴ Study authors attribute ob-gyns' high degree of appropriateness to the specialty's "relatively high degree of consensus" on imaging usage. Radiology and other specialties trailed in comparison. When broken down by diagnostic code, obstetric ultrasound was second only to mammography in overall appropriate usage at 86%. Ultrasound, generally, had an appropriateness score of 84%, far ahead of MRI and CT, both at 56%.

Defensive Medicine

Some imaging utilization growth, particularly within high-risk specialties like ob-gyn and in states that have not enacted tort reform, is undoubtedly attributable to the practice of defensive medicine. The fear of being sued leads physicians to sometimes perform additional procedures or tests, or refer to specialists.¹⁵ Some estimates of defensive medicine costs, as a whole, run as high as \$60-100 billion a year. It costs the federal government billions of dollars in Medicare and Medicaid spending and raises the cost of health care for every American.

¹⁴ TG Dehn, B O'Connell, RN Hall, and T Moulton. Appropriateness of Imaging Examinations: Current State and Future Approaches. *Imaging Economics*. March/April 2000.

¹⁵ Common Good and Harris Interactive. *Fear of Litigation Study: The Impact on Medicine*. Common Good, March 4, 2002.

The fear of being sued is justified. ACOG surveys members regularly on the issue of medical liability. According to preliminary data from the 2006 ACOG Survey on Professional Liability, the typical ob-gyn can expect to be sued 2.3 times over his or her career.¹⁶ In fact, 89.2% of ob-gyns reported they had been sued at least once so far. Over one-third (37.3%) have been sued for care provided during their residency.

This high rate of legal activity does not equate to widespread malpractice. Rather, it demonstrates a lawsuit culture where doctors are held responsible for a less than perfect outcome. And in obstetrics, there is no guarantee of a perfect outcome, no matter how perfect the prenatal care and delivery.

A study published in the Journal of the American Medical Association surveyed physicians in 6 high-risk specialties in Pennsylvania and found that nearly all of them practiced defensive medicine (93%).¹⁷ Within this group, 43% who detailed their most recent defensive act cited using imaging. This was true of a smaller but significant percentage of ob-gyns (18%).

Ultrasound adds a layer of reassurance to many ob-gyns and to their patients. Until Congress acts to solve America's medical liability crisis, the costs of defensive medicine, including imaging, will continue to grow.

Ultrasound is Different: Current Proposals Are Not Necessary for Ultrasound

Accreditation and Privileging

Some have offered proposals to require accreditation of physician practices in Medicare and in the private sector, or privileging beyond board certification.

16 American College of Obstetricians and Gynecologists. 2006 ACOG Survey on Professional Liability. (Preliminary unpublished data) The 2006 ACOG Survey on Professional Liability administered between January 23 and March 20, 2006 by the American College of Obstetricians and Gynecologists. Results based on responses to self-administered mailed and electronic questionnaires. National response rate = 37%.

17 DM Studdert, et al. Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment. JAMA. 2005; 293: 2609-2617.

Accreditation measures are unnecessary for ob-gyns, or other specialists, who are trained in ultrasound from the beginning of their residency and use it continuously and accurately throughout their medical career. Accreditation of medical practices is typically done to reduce exposure to radiation and to certify that technologists are using radiating equipment properly. This is not relevant to ultrasound, which doesn't use radiation.

Accreditation would also set a dangerous precedent of government intervention in patient care. If a physician needs special certification for ultrasound, then where would government accreditation regulations end? It would be unthinkable to parse medical practice into multiple government accreditation programs for each facet of clinical care, but that is just what is being proposed here.

Accreditation of ultrasound, an essential tool of private practice physicians, would be much more burdensome than accreditation for advanced imaging, largely found in imaging centers. Ultrasound is widely dispersed in physician offices. Harvey Klein, Ph.D. of Klein Biomedical Consultants, a long-time ultrasound industry analyst, estimates that as many as 85 - 90% of ob-gyn offices in the United States have ultrasound on site for use in managing the care of their patients. One-quarter of ob-gyns are in solo practice and the mean practice size is three. These physicians do not have the office support staff on hand to manage the process of accreditation, unlike multi-million dollar imaging centers.

Furthermore, physician specialty societies, including ACOG, are already taking quality assurance measures, including participation in voluntary accreditation through the American Institute of Ultrasound in Medicine. Imposing a new layer of federal regulation on physicians will only increase practice expenses and require additional federal resources at CMS—already stretched beyond its means—for verification.

No federal certification or accreditation standards can guarantee that the right diagnostic test is provided in the right setting at the right time. This can only be accomplished through training programs and appropriateness recommendations, like those in use through ACOG.

Ultrasound has undeniable benefits for both patients and physicians needing prompt diagnosis and timely treatment. Its safety is unquestioned. Ultrasound is used appropriately in clinical settings. And it is growing at a slower rate than other Medicare imaging services and all Part B services generally. There is no compelling reason for the government to subject physicians, many in small practices and having many years of experience, to burdensome new accreditation requirements.

In-Office Ancillary Exception

Removal of the in-office ancillary services exception of the Stark Law (42 USC §1935nn) is an overly broad remedy, particularly in ultrasound. This change would restrict in-office diagnostic testing and result in substantial inconvenience and costs for patients, who would have to schedule a new appointment, with a different facility and a different physician, when the needed testing could be performed on the spot by the patient's own physician. Continuity of care would be interrupted, and the treating physician would lose valuable time in detecting and diagnosing a condition. An ob-gyn unable to perform ultrasonography would also lose the benefit of seeing real-time images, important in assessing fetal movement and blood flow.

Maryland's self-referral law--one of the toughest in the country--allows only radiology to self-refer for MR, CT and radiation therapy procedures, effectively limiting ownership of these technologies by nonradiologists. The law specifically excludes ultrasound. To the best of our knowledge, no state legislature has considered restricting in-office ultrasound.

Adopting the IDTF Certification Program in the Physician Office

Another proposal would expand certification requirements of independent diagnostic testing facilities (IDTFs) to the physician office. The IDTF certification program allows individual Medicare carriers to determine which specialties are able to supervise imaging exams, listed by CPT code. This approach would create a de facto privileging program under Medicare that is based on the physician's specialty rather than the training and experience of any specific physician or the guidelines that are derived by each specialty organization for its members. If applied to physician offices, ob-gyns in 12 Western states that use the carrier Noridian would be barred from supervising obstetric ultrasound, simply because they are not radiologists. The Medicare carrier in Wisconsin is considering similar restrictions for mobile imaging units.

Barring ob-gyns from performing ultrasound would clearly harm patient care. It also offers no protection from cost increases. The MRI, CT, and PET utilization growth in IDTFs far outpaces the utilization growth of these services in physicians' offices. MedPAC found that Medicare spending for IDTF services (mainly CT and MRI) nearly doubled between 2000 and 2002, from \$385 million to \$741 million.¹⁸ Medicare spending for all imaging services paid under the physician fee schedule grew at half that rate during the same period. MedPAC further found that Medicare spending for IDTF services grew by almost 40 percent per year, on average, during this period—a growth rate that cannot be explained due to the conservative growth in the number of new IDTFs.

Adjusting the Medicare Allowances for Use of Equipment and Interest Rates

In part of its calculation of the capital costs of equipment, Medicare assumes that imaging equipment is in use 50% of the time. CMS and MedPAC are investigating whether this

¹⁸ MedPAC June 2004 Data Book.

assumption should be changed to a higher rate, a change ACOG would oppose. Ultrasound services are one element of the clinical care provided by physicians whose primary occupation is direct patient care - i.e. surgical procedures and office visits. Ultrasound equipment remains idle when physicians are engaged in other patient care activities, lowering its overall use rate. Breast surgeons, for example, will often have an ultrasound unit in their office for use on the one day a week that they perform ultrasound-guided needle biopsies and ultrasound-guided cyst aspirations in their offices. MRI and CT, on the other hand, are more often used in a radiology practice setting where imaging is the only type of care provided, and unlikely to sit idle during business hours.

Given this use model for ultrasound equipment, we recommend that Congress direct CMS to maintain the 50% utilization rate for ultrasound equipment in order to maintain access to these important services for Medicare beneficiaries, even if CMS decides to change the utilization rate for other types of imaging equipment.

CMS indicated in its 2007 Medicare Physician Fee Schedule Notice of Proposed Rulemaking regarding practice expense that it currently utilizes an interest rate of 11% in calculating the cost of capital for medical equipment purchases. MedPAC, using commercial loan rates rather than medical equipment loan rates, argued during its April 2006 meeting that this rate is overly generous. Data obtained from Key Equipment Financing supports the accuracy of Medicare's current interest rate allowance. The last several years have seen historically low interest rates. During this time period the interest rate on the ultrasound equipment has ranged from 8%-10% (depending on the term and structure). In the last six months the low interest environment has changed, with the Federal Reserve Board boosting rates several times. As a result, rates have increased to 9%-11%. Before making any change on

this interest rate, MedPAC or CMS should investigate the issue more fully by surveying a range of medical equipment financing companies.

Conclusion

Physicians in many specialties are trained in ultrasound from day one of their residency. ACOG and other specialty societies have shown leadership in developing appropriateness criteria and getting it into practice, and evidence of appropriateness shows that these efforts are working. Growth in ultrasound is low and driven by factors largely out of a physician's control, such as the increase in incidence of chronic disease and the tort climate. Setting it apart from other imaging services, ultrasound has an unquestioned record of safety, is fully integrated in day-to-day patient care, and is saving our health care system money every day through early detection and fewer invasive procedures.

A distinction between ultrasound and the rest of the imaging field is warranted. We urge the Congress, in any legislation, to recognize the safety, quality and appropriateness of ultrasound studies and to exempt ultrasound from any new restrictions on imaging use, federal quality standards, or additional administrative burdens.

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